



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

HL

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/139,386 08/25/98 MONFORTE J GETR.031-STA

ARNOLD WHITE & DURKEE
P O BOX 4433
HOUSTON TX 77210

HM12/0225

| EXAMINER |
|----------|
|----------|

TUNG, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1656

10

DATE MAILED:

02/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/139,386

Applicant(s)

Monforte et al.

Examiner

Joyce Tung

Group Art Unit

1653

☒ Responsive to communication(s) filed on Oct 8, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-87 is/are pending in the application.

Of the above, claim(s) 22-87 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-87 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1653

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1653.

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-21 in Paper No. 9 is acknowledged. Claims 22-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected Group II-III.

Information Disclosure Statement

2. The references A3 and C22 lined through were not considered, because the references were not found in SN 08/445,751 and 08/639,363.

Specification

3. The title of the invention is not descriptive, the old title is directed to oligonucleotide sizing cleavable primers. The claim language is directed to a primer having 5' end which has an immobilization attachment site and 3' end which has a chemically cleavable site and is capable of being extended by an enzyme. A new title is required that is clearly indicative of the invention to which the claims are directed.

Art Unit: 1653

Claim Rejections - 35 U.S.C. § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-9 and 11-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,547,835) in view of Richards et al. (5,427,929).

Koster et al. disclose a nucleic acid sequence method using mass spectrometry in which polymerase chain reaction is used to form the four base specific sets of DNA fragments (see column 1, lines 61-65). The primer at 5' end has a linker including a spacer with sufficient length attaching to a solid support (see column 11, lines 51-56). The immobilized products on the solid support can be washed to remove the unbound things (see column 11, lines 59-60). The linker is cleaved and the fragments are subjected to a mass spectrometry (see column 12, lines 1-10). The

Art Unit: 1653

solid support bound base sequence can be modified by thio-modification (see column 12, lines 58-60). The linker chemistry can be a biotin/streptavidin system (see column 13, lines 15-31).

MALDI mass spectrometry with a time-of-flight mass analyzer is used for DNA sequence (see column 14, lines 47-67). Various solid supports can be used, for example, glass fiber filter. (see column 14, lines 5-18). The four dideoxy nucleotides are used for the base termination of the primer extension reaction (see column 10, lines 13-25). Example 17 (see column 31) teaches the incorporation of alpha-thiotriphosphate to generate primer extension products containing phosphorothioate linkages followed by treatment with 2-iodoethanol for cleavage (See column 32, lines 1-14).

Koster et al. do not disclose using a primer with a 3' end chemically cleavable site and is capable of being extended by an enzyme. However, Koster et al. do disclose cleaving the immobilized amplified products via the chemical cleavage of an incorporated alpha-thiotriphosphate (See column 13, example 17). Incorporating modified base into an amplified nucleic acid products via polymerase chain reaction with a modified primer was well known in the art at the time of the instant invention (See Richards et al. 5,427,929, column 7, lines 29-33 and column 9, lines 55-68 and column 10, line 1).

The teachings of Koster et al. and Richards et al. suggest the limitations of the instant claims 1-9 and 11-21. The instant claims 1-9 and 11-21 are drawn to a primer comprising a 5' end containing an immobilization site and 3' end containing a chemically cleavable site and capable of being extended by an enzyme. The chemical cleavage site comprises a modified base and

Art Unit: 1653

modified sugar and is selected from 3'-(S)-phosphorathioate. The immobilized site comprises a solid support bound to an intervening arm which has six or more atoms in length and the solid support is as claimed in claim 14. The functional group is avidin and streptavidin.

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the references of Koster et al. and Richards et al. to make the primer as claimed because the primer of Koster et al. used has a cleavable site with disulfide bond modification to increase mass spectrometric performance (See column 13, lines 3-35), but the modification is not on the 3' end of the primer and based upon the teachings of Richards et al. a chemical cleavage site can be incorporated into an amplified products by a modified primer and the method of Richards et al. is efficient and economy (See the Abstract). It would have prima facie obvious to make the primer as claimed.

6. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster (5,547,835) in view of Richards et al. (5,427,929) and Wu et al. (Genomics 1989, Vol. 4, pg. 560-569).

The teachings of Koester et al. and Richards et al. are set forth in section 5 above.

Koster does not disclose a ligase used in a primer extension reaction.

Wu et al. disclose a ligase used in nucleic acid amplification reaction. (see pg. 561).

The teachings of Koester et al., Richards et al, and Wu et al. suggest the limitations of the instant claims 1 and 9 in which a ligase is used in a primer extension reaction.

Art Unit: 1653

One of ordinary skill in the art at the time of the instant invention would have been motivated to combine the references of Koster et al., Richards et al. and Wu et al. by using a ligase in a primer extension reaction as taught by Wu et al. for a reasonable expectation of success because it was well known in the art. It would have been prima facie obvious to make the primer as claimed.

7. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached at (703) 308-1152.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1653 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

February 9, 2000


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600